UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/216,242	12/18/1998	JOHN M. LIPARI	6439.US.01	1025

7590 12/03/2001

MARTIN L. KATZ
ROCKEY, MILNAMOW & KATZ
TWO PRUDENTIAL PLAZA
180 NORTH STETSON AVENUE, SUITE 4700
CHICAGO, IL 60601

EXAMINER
KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
1615	21

DATE MAILED: 12/03/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/212,242	Applicant(s) Lipari
	Examiner Gollamudi S. Kishore, Ph.D	Art Unit 1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Sep 24, 2001* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1, 3-5, 12, 14-17, 19, and 20* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1, 3-5, 12, 14-17, 19, and 20* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

The associate power of attorney and the amendment filed on 9-~~20~~24-01 are acknowledged.

Claims included in the prosecution are 1, 3-5, 12, 14-17 and 19-20.

Claim Rejections - 35 U.S.C. § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> **A person shall be entitled to a patent unless --**
>
> **(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.**

2. Claims 1, 3-5, 12, 14-17 and 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Lacy (5,645,856).

Lacy discloses capsules containing emulsions of fenofibrate. The emulsions contain a triglyceride, propylene glycol fatty acid esters, polyglyerol esters of fatty acids and a cosolvent; the composition further contains Capric/caprylic triglycerides such as Miglycol and Captex (note columns 4 and 5 and Examples 6 and 7).

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant while acknowledging that Lacy discloses caprylic/capric

triglycerides (medium chain esters) argue that these materials are not structured lipids which are lipids containing saturated medium and long chain fatty acids esterified on the same glycerol molecule. This argument is very confusing because Lacy teaches the same triglycerides which are listed on page 3, lines 34-39. Even assuming that Lacy does not teach saturated lipids, the examiner points out that page 3, lines 34-39 do not provide specific definition of the term, 'structured lipids". For instance, at this site applicant recites expressions such as " Representative structured lipids include, but not limited to, ---", " -- and in general, include those lipids containing saturated medium and long chain fatty acids----". These statements do not represent absolute requirement for the presence of saturated fatty acids in the glycerol moiety (in fact, linoleic acid recited at this location is an unsaturated fatty acid).

Claim Rejections - 35 U.S.C. § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.**

4. Claims 1,3-5, 12, 14-17 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lacy cited above by itself or in combination Sanchez (5,494,936).

As pointed out above, Lacy discloses capsules containing emulsions of fenofibrate. The emulsions contain a triglyceride, propylene glycol fatty acid esters, polyglyerol esters of fatty acids and a cosolvent; the composition further contains Capric/caprylic triglycerides such as Miglycol and Captex (note columns 4 and 5 and Examples 6 and 7). Lacy does not teach all the structured lipids (triglycerides). However, it is deemed obvious to one of ordinary skill in the art to use any triglyceride based on the guidance provided by Lacy with the expectation of obtaining similar results. One of ordinary skill in the art would be motivated to use any triglyceride since Sanchez teaches the use of triglycerides for the lipid regulating agent probucol. Lacy also does not specifically teach through examples the method of treatment of hyperlipidemia using an effective amount of the fenofibrate. Since the compound is a known lipid metabolism regulating agent, it is deemed obvious to one of ordinary skill in the art to use the formulations for the lipid regulating purposes.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant's arguments once again based on structured lipids. These have been addressed above.

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.

Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

November 30, 2001